Remarks

This paper responds to the Office Action mailed May 6, 2011, which considered claims 1, 2, 5, 6, 9, 10, 14, 17-19, 22, and 25-28, with claims 3, 4, 11-13, 15, 16, 23, and 24 withdrawn from consideration as allegedly directed to a nonelected invention. Applicants do not amend, cancel, or add any claims with this paper.

Information Disclosure Statements

Applicants thank the examiner for considering the IDS filed February 25, 2011.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Action rejects claims 9 and 22 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Action asserts that these claims require fine bone powder to have a diameter less than or equal to 50 microns, but the claims from which they depend require sub-micron particle diameters.

In response, Applicants respectfully submit the Office has apparently misinterpreted or misunderstood the claims. Claims 9 and 22 further define the "average diameter" to be 50 microns or less. However, even if the fine bone powder "comprises sub-micron" particles (claim 1), an average particle diameter can still be 50 microns or less. Accordingly, claims 9 and 22 properly further limit the claims from which they depend and are not indefinite.

Claim Rejections – 35 U.S.C. § 103(a)

The Action rejects claims 1, 9, 10, 14, 17, 22, and 25 over Boyce et al. (U.S. Patent No. 5,899,939) in view of Chou (U.S. Application Publication No. 2004/0191292). Applicants disagree with the rejection for the reasons that follow.

Claim 1 recites a bone-powder-impregnated, porous structure comprising a porous matrix made of a biocompatible material impregnated with fine bone powder obtained by pulverizing living bones and/or teeth, the diameters of said fine bone powder particles including sub-micron. Claim 17 recites a bone-powder-impregnated, surface-roughened structure comprising a surface-roughened matrix made of a biocompatible material, which is impregnated with fine bone powder obtained by pulverizing living bones and/or teeth, the diameters of said fine bone powder particles including sub-micron. The structures recited in claims 1 and 17 can regenerate a large amount of bone from a small amount of bone. (Specification, page 9, line 28 to page 10, line 3.)

Boyce et al. discloses a bone-derived implant which comprises a plurality of superimposed layers assembled with an adhesive into a unitary structure, at least one layer in the structure being a compression strength-imparting layer fabricated from non-demineralized cortical bone or partially demineralized cortical bone. Boyce et al. teaches that a bone-derived implant can possess one or more cavities, which can be partially or completely filled with one or more medically/surgically useful substances such as bone or demineralized bone powder (column 4, lines 53-64, and column 5, lines 15-16). However, Boyce et al. fails to teach that the demineralized bone powder comprises sub-micron particles.

The Action asserts that it is the examiner's position that demineralization results in a similar structured bone powder that resulting from pulverizing. In support of this conclusion, the examiner asserts that the specification teaches pulverizing and demineralizing as alternative processes to produce bone powder, but does not distinguish between any specific characteristics of these methods.

Applicants respectfully submit that the present specification does not teach that pulverizing and demineralizing are alternative processes to produce bone powder. If the Office asserts this position, Applicants submit that it bears the

burden of at least citing to page and line numbers in Applicants' specification where support for such assertions is allegedly found. The Action fails to show such support and the rejection is deficient on its face for at least this reason.

Still further, Applicants note that demineralization is a chemical process, whereas pulverization is a physical process. The former results in a chemical change in the underlying structure through a chemical reaction; the latter does not. Again, if the examiner wishes to assert the two processes result in equivalent structures, he is respectfully requested to provide some art-based support for his position. As it stands, the examiner has made a naked, completely unsupported assertion. The rejection is deficient for at least this reason as well.

Applicants note that the present claims require a structure obtained by pulverizing living bones and/or teeth. Boyce et al. teaches (at best) pulverizing demineralized bones. If the Office wishes to maintain this rejection, *it* bears the burden of establishing that the presently claimed produced (obtained by pulverizing living bones and/or teeth) would inherently be present in Boyce et al. In other words, the Office must set forth some reasonable explanation (i.e., supported by the art) that pulverized demineralized bone product would be identical in all material respects to the presently claimed product obtained by pulverizing living bones and/or teeth. Applicants submit that the Office has failed to meet its burden.

Still further, Applicants wish to point out that handling and pulverizing living bone and/or teeth material to produce a product including sub-micron particles is difficult. It would not have been obvious to modify any of the prior art that uses a demineralized bone product to use a living bone or tooth product and to pulverize to produce a product including sub-micron particles.

Regarding the secondary document of Chou, Applicants note that this document discloses scaffolds for human bone tissue engineering, which comprise a

silicon-containing inorganic element microparticle as a bioactive inducing substance, and an organic polymer as a carrier, and have a three-dimensional structure comprising both micropores and connecting channels (see claim 1). The silicon-containing inorganic element microparticles may be silicon/calcium/phosphorus microparticles, wherein the silicon/calcium/phosphorus microparticles have a diameter of less than or equal to 10 microns, preferably less than 1000 nm, more preferably less than 100 nm, and most preferably in the range of 5-80 nm, so that the microparticles are embedded evenly in the organic polymer, and are slowly and uniformly released during the degradation of the organic polymer. (Paragraph [0024].) Chou further discloses that the silicon/calcium/phosphorus microparticles are prepared by mixing microparticles of each of the three elements according to the atomic contents of 60-100% silicon, 0-30% calcium, and 0-20% phosphorus.

The Action asserts that it would have been obvious to one of ordinary skill to modify the bone powder of Boyce to have a sub-micron size as taught by Chou in order to embed the particles evenly within the matrix. Regardless of whether this is true or not (and Applicants do not agree that it is), Applicants submit that the present invention would not result because Boyce et al. does not teach pulverizing living bones and Chou does not remedy this significant deficiency. Moreover, there is nothing in Chou that would lead one skilled in the art to modify the teaching of Boyce et al. to change from a demineralized bone product to a living bone product.

For at least the foregoing reasons, Applicants submit that Boyce et al. and Chou fail to render obvious the presently claimed invention.

The Action further rejects claims 1, 2, 5, 6, and 17-19 over Smith et al. (U.S. Application Publication No. 2004/0253279) in view of Boyce et al. and further in view of Chou.

Applicants note that this rejection is based on the same premise that the rejection above is based: that pulverization of demineralized bones produces a product that is identical in all material respects to pulverization of living bones and/or teeth. That is, the Action asserts that Smith et al. teaches pulverization of demineralized bones, and that this anticipates the product produced by pulverization of living bones and/or teeth of the present claims. For the reasons set forth above, this rejection is deficient and must be withdrawn.

The Action further rejects claim 26 as obvious over Boyce et al. in view of Chou and further in view of Takagi et al. (U.S. Patent No. 4,654,314).

Here again, the Action relies for Boyce et al. for a teaching it does not provide. Chou and Takagi et al. fail to remedy this deficiency. Accordingly, this rejection is also deficient and must be withdrawn.

The Action further rejects claims 27 and 28 as unpatentable over Boyce et al. in view of Chou and further in view of Levine et al. (U.S. Application Publication No. 2003/0220696).

Again, the Action relies for Boyce et al. for a teaching it does not provide. Chou and Levine et al. fail to remedy this deficiency. Accordingly, this rejection is also deficient and must be withdrawn.

In view of the foregoing remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the claims. If there are any issues that can be resolved by telephone discussion, Applicants invite the examiner to contact the undersigned attorney.

Respectfully submitted,
Makoto OGISO et al.

/Sean Myers-Payne/
Reg. No. 42,920
Sean Myers-Payne

Bruce H. Bernstein
Reg. No. 29,027

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GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191